

## § 118.7

## 21 CFR Ch. I (4–1–12 Edition)

law requires that these eggs must be treated to achieve at least a 5-log destruction of *Salmonella* Enteritidis or processed as egg products in accordance with the Egg Products Inspection Act, 21 CFR 118.6(f).” The statement must be legible and conspicuous.

### § 118.7 Sampling methodology for *Salmonella* Enteritidis (SE).

(a) *Environmental sampling.* An environmental test must be done for each poultry house in accordance with § 118.5 (a) and (b). Within each poultry house, you must sample the environment using a sampling plan appropriate to the poultry house layout.

(b) *Egg sampling.* When you conduct an egg test required under § 118.6, you must collect and test the following number of eggs from the positive poultry house:

(1) To meet the egg testing requirements of § 118.6(c), you must collect and deliver for testing a minimum of 1,000 intact eggs representative of a day’s production. The 1,000-egg sample must be tested according to § 118.8. You must collect and test four 1,000-egg samples at 2-week intervals for a total of 4,000 eggs.

(2) To meet the monthly egg testing requirement of § 118.6(e), you must collect and deliver for testing a minimum of 1,000 intact eggs representative of a day’s production per month for the life of the flock. Eggs must be tested according to § 118.8.

### § 118.8 Testing methodology for *Salmonella* Enteritidis (SE).

(a) *Testing of environmental samples for SE.* Testing to detect SE in environmental samples must be conducted by the method entitled “Environmental Sampling and Detection of *Salmonella* in Poultry Houses,” April 2008, or an equivalent method in accuracy, precision, and sensitivity in detecting SE. The April 2008 Environmental Sampling and Detection of *Salmonella* Web site is located at <http://www.fda.gov/Food/ScienceResearch/LaboratoryMethods/ucm114716.htm>, current as of June 26, 2009. The Director of the Federal Register approves the incorporation by reference of “Environmental Sampling and Detection of *Salmonella* in Poultry Houses,” April 2008,

in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The FDA will request approval to incorporate by reference any updates to this Web site. The FDA will change the date of the Web site in this paragraph with each update. You may obtain a copy from Division of Microbiology (HFS-710), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-2364, or you may examine a copy at the Center for Food Safety and Applied Nutrition’s Library, 5100 Paint Branch Pkwy., College Park, MD, 301-436-2163, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: [http://www.archives.gov/federal\\_register/code\\_of\\_federal\\_regulation/ibr\\_locations.html](http://www.archives.gov/federal_register/code_of_federal_regulation/ibr_locations.html).

(b) *Testing of egg samples for SE.* Testing to detect SE in egg samples must be conducted according to Chapter 5 of FDA’s Bacteriological Analytical Manual (BAM), December 2007 Edition, or an equivalent method in accuracy, precision, and sensitivity in detecting SE. Chapter 5 of FDA’s Bacteriological Analytical Manual, December 2007 Edition, is located at <http://www.fda.gov/Food/ScienceResearch/LaboratoryMethods/BacteriologicalAnalyticalManualBAM/ucm070149.htm>, current as of June 26, 2009. The method is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The FDA will request approval to incorporate by reference any updates to this Web site. The FDA will change the date of the Web site in this paragraph with each update. You may obtain a copy from Division of Microbiology (HFS-710), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-2364, or you may examine a copy at the Center for Food Safety and Applied Nutrition’s Library, 5100 Paint Branch Pkwy., College Park, MD, 301-436-2163, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: [http://www.archives.gov/federal\\_register/](http://www.archives.gov/federal_register/)

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ibr\_locations.html.*

**§ 118.9 Administration of the Salmonella Enteritidis (SE) prevention plan.**

You must have one or more supervisory personnel, who do not have to be on-site employees, to be responsible for ensuring compliance with each farm's SE prevention plan. This person must have successfully completed training on SE prevention measures for egg production that is equivalent to that received under a standardized curriculum recognized by the Food and Drug Administration or must be otherwise qualified through job experience to administer the SE prevention measures. Job experience will qualify this person to perform these functions if it has provided knowledge at least equivalent to that provided through the standardized curriculum. This person is responsible for:

- (a) Development and implementation of an SE prevention plan that is appropriate for your specific farm and meets the requirements of § 118.4;
- (b) Reassessing and modifying the SE prevention plan as necessary to ensure that the requirements in § 118.4 are met; and
- (c) Review of records created under § 118.10. This person does not need to have performed the monitoring or created the records.

**§ 118.10 Recordkeeping requirements for the Salmonella Enteritidis (SE) prevention plan.**

(a) *Records:* You must maintain the following records documenting your SE prevention measures:

- (1) A written SE prevention plan required by § 118.4;
- (2) Documentation that pullets were "SE monitored" or were raised under "SE monitored" conditions, including environmental testing records for pullets, as required by § 118.4(a)(2);
- (3) Records documenting compliance with the SE prevention measures, as follows:
  - (i) Biosecurity measures;
  - (ii) Rodent and other pest control measures;
  - (iii) Cleaning and disinfection procedures performed at depopulation, when applicable;

- (iv) Refrigeration requirements;
- (v) Environmental and egg sampling procedures, when applicable, performed under § 118.7;
- (vi) Results of SE testing, when applicable, performed under § 118.8 as required in §§ 118.4(a)(2), 118.5, and 118.6;
- (vii) Diversion of eggs, if applicable, as required in § 118.6; and

(viii) Eggs at a particular farm being given a treatment as defined in § 118.3, if you are a producer complying with the requirements of this section as described in § 118.1(a)(2).

(4) Records of review and of modifications of the SE prevention plan and corrective actions taken.

(b) *General requirements for records maintained by shell egg producers.* All records required by § 118.10(a) must include:

- (1) Your name and the location of your farm,
- (2) The date and time of the activity that the record reflects,
- (3) The signature or initials of the person performing the operation or creating the record. The written SE prevention plan must be dated and carry the signature(s) (not initials) of the person(s) who administers the plan as described in § 118.9, and

(4) Data and information reflecting compliance activities must be entered on records at the time the activity is performed or observed, and the records must contain the actual values observed, if applicable.

(c) *Length of time records must be retained.* You must retain all records required by this part at your place of business, unless stored offsite under § 118.10(d), for 1 year after the flock to which they pertain has been taken permanently out of production.

(d) *Offsite storage of records.* You may store the records required by this part, except for the written SE prevention plan, offsite. You must be able to retrieve and provide the records at your place of business within 24 hours of request for official review. Electronic records are considered to be onsite if they are accessible from an onsite location.

(e) *Official review of records.* You must have all records required by this part available for official review and copying at reasonable times.